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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,647	03/02/2004	Robert E. Fischell	CRD-946 DIV	3069
27777	7590	11/01/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			DAVIS, DANIEL J	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/791,647

Applicant(s)

FISCHELL ET AL.

Examiner

D. Jacob Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 41-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION**

If applicants traverse the rejection on the grounds that one of the references were commonly owned at the time of the invention, as recited in U.S.C. 103(c), examiner requests information under Rule 1.105. Specifically, examiner requests that applicants submit the status of every patent and publication wherein Robert E. Fischell is at least a co-inventor, i.e., whether each patent or publication may or may not be applied against the present application under U.S.C. 103(a) as precluded by U.S.C. 103(c).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen Cornelius et al. (US 6,068,634) in view of Christian et al. (US 5,174,295). Lorentzen discloses a primary stenting system (Fig. 9) comprising a flexible guidewire (Col. 5, line 60), a balloon catheter having an inflatable balloon 114, a polyurethane distal tip 117 (Col. 4, lines 41-45), a lumen 118, a stent 120, and proximal and distal elastomeric bands 122 and 124. The reference is silent with respect to the flexibility of the tip.. Christian teaches that the tip should be flexible to "not cause trauma in the vessel in which it is advanced" (column 17, lines 15-17). Therefore, it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tip flexible to minimize the risk of trauma to the vessel wall. Lorentzen discloses that the tip comprises a gentle taper from a larger to a smaller diameter, and “the gently tapered distal tip and distal elastomer band together form[ing] a smooth outer surface to facilitate penetration of a tight stenosis.

Claims 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen in view of Fischell et al. (US 5,792,144). Lorentzen discloses a tapered tip 117 but is silent with respect to the flexibility or the exact length or taper of the tip. Fischell discloses that the tip may flexible, supposedly to prevent trauma to the vessel wall. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Lorentzen tip flexible to prevent trauma to the vessel wall.

Furthermore, Fischell discloses a flexible tapered tip having a tapered slope of less than 4 degrees (Col. 6, line 23) and a length that is greater than 10 mm to penetrate a stenosis (Col. 5, line 21). Although the patent does not disclose the length of the tip being greater than 20 mm, such a length would also be obvious to one of ordinary skill in the art to effectively penetrate a stenosis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make Lorentzen's tip 117 greater than 10 mm as taught by Fischell to effectively penetrate a stenosis, and even greater than 20 mm which also would effectively penetrate a stenosis. Moreover, it would have been obvious to one of ordinary skill in the art to adjust Lorentzen's tapered tip to have a slope of less than 4 degrees as taught by Fischell to also penetrate a stenosis.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen in view of Wang et al. (US 6,221,097). Lorentzen discloses elastomer bands but is silent regarding a lubricous coat. Nevertheless, Wang discloses elastomer sleeves that are coated with a lubricant (Col. 2, lines 2-20) to facilitate the release of the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to lubricate Lorentzen's bands 122 and 124 as taught by Wang to facilitate the release of the stent.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen in view of Drewes, Jr. et al. (US 5,300,048). Lorentzen discloses bands 122 and 124 made of an elastomer, but fails to disclose a high density material included in the elastomer bands to increase radiopacity. Nevertheless, Drewes discloses that high density materials such as tungsten, may be added to an elastomeric material to increase radiopacity (Col. 2, lines 15-21). The increased radiopacity of the bands helps monitor catheter location. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a high density material to Lorentzen's bands 122 and 124 as taught by Drewes to increase radiopacity, in turn helping to monitor catheter location.

### ***Response to Arguments***

Applicants traverse the rejection on the grounds that Lorentzo fails to disclose or suggest a flexible tip. Christian teaches that flexible tips are desirable since they prevent trauma to the vessel wall.

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Applicants further traverse that it would not be obvious to modify the Lorentzo reference in view of Fischell since they are accomplishing the same end, but by different means. Examiner maintains that Fischell teaches advantages to forming an elongated sloping tip and that one of ordinary skill in the art would be motivated thereby to modify the Lorentzo reference in the same manner.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

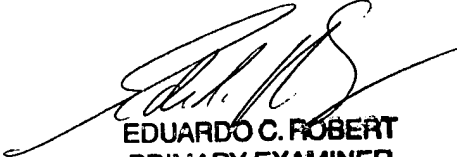
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (571) 272-4693. The examiner can normally be reached on M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD



**EDUARDO C. ROBERT**  
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